SUPPLEMENTS FOR METHODOLOGICAL INNOVATIONS IN THE BEHAVIORAL AND SOCIAL SCIENCES

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Department of Health and Human Services (DHHS)

PARTICIPATING ORGANIZATION:
National Institutes of Health (NIH)
(http://www.nih.gov)

This RFA is developed as an NIH Roadmap initiative (http://nihroadmap.nih.gov/). All NIH Institutes and Centers participate in Roadmap initiatives. The RFA will be administered by the National Institute of Child Health and Human Development (NICHD) on behalf of the NIH.

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER(S) 93.864

LETTER OF INTENT RECEIPT DATE: January 13, 2004
APPLICATION RECEIPT DATE: February 13, 2004

THIS RFA CONTAINS THE FOLLOWING INFORMATION

PURPOSE OF THIS RFA

The Institutes, Centers and Offices of the National Institutes of Health (NIH) invite NIH-funded investigators to submit supplemental research grant applications to develop

methodological innovations in the behavioral and social sciences. These modest supplements will support the addition of a methodological development component to already-funded NIH research projects.

Methodology issues include research design, data collection techniques, measurement, and data analysis techniques in the social and behavioral sciences. The goal of this RFA is to encourage methodological and technological innovation that will improve the quality and scientific power of data collected in the behavioral and social sciences. Development of methodology and technology for multidisciplinary, interdisciplinary, multimethod, and multilevel analytic approaches that integrate behavioral and social science research with biomedical research is particularly encouraged.

PROGRAM OBJECTIVES

The National Institutes of Health (NIH) are engaged in a series of activities collectively known as the "NIH Roadmap". The Roadmap's goal-- in keeping with the NIH mission of uncovering new knowledge about the prevention, detection, diagnosis, and treatment of disease and disability -- is to accelerate both the pace of discovery in these key areas and the translation of therapies from bench to bedside. In the course of developing the NIH Roadmap, it has become clear that increasingly, scientific advances are being made at the interfaces of traditional disciplines, and that approaches to science are becoming more integrative. (Additional information about the NIH Roadmap can be found on the NIH website at http://nihroadmap.nih.gov/).

The behavioral and social sciences have broad significance and are fundamental to the comprehensive understanding of disease etiology and treatment as well as to promotion of health and well-being. Behavioral and social factors have a significant impact across the lifespan on diseases ranging from cardiovascular disease, to cancer, to diabetes, and to oral and mental health. The development of innovative methodology and technology in the behavioral and social sciences will allow investigation of the full impact of these factors on health and facilitate the performance of interdisciplinary research at the intersection of the behavioral, social and biomedical sciences.

RESEARCH OBJECTIVES

This Request for Applications encourages applications to develop innovative methodology in four general areas of social and behavioral sciences research. These areas, discussed in detail below, include research design, data collection techniques, measurement, and data analysis techniques. Each application is not expected to focus on all four of these areas; an application may focus on only one of the four areas and still be responsive to this RFA.

Examples of methodological and measurement development congruent with the intent of this RFA include, but are not limited to, the following:

o Multidisciplinary, interdisciplinary, multimethod, and multilevel research designs for use in behavioral and social science research, with special emphasis on both the development of new technologies and the analytical complexities associated with the integration of behavioral, social, genetic, and biomedical data (e.g., developing new measures to study gene-environment interactions).

o Improved methods for performing research on diverse populations (e.g., populations that are distinctive by virtue of age, gender, sexual orientation, ethnicity, culture, socio-economic status, literacy, language, or disability) or on potentially sensitive or covert behaviors such as drug use, abuse, and violence.

o Innovative experimental designs to study how changes in economic, social, environmental, physical, or political context affect all aspects of ongoing research, including, but not limited to research design, measurement, data collection, and analytic strategies.

o Multidisciplinary and interdisciplinary approaches that allow applicants to explore the ideas and methods developed in social science and behavioral fields other than their own are encouraged. Particular emphasis is placed on the development and integration of behavioral and social sciences measures with those of the biomedical disciplines. Consulting relevant literature and collaborating with colleagues from other disciplines may provide important opportunities for developing improved methodology and measurement to better understand the impact of behavioral and social factors on disease and health.

A. RESEARCH DESIGN

Broadly stated, research design determines how well a research plan can accomplish stated purposes and test hypotheses. Research design encompasses many decisions including the sampling plan; selection of appropriate study designs, methods, procedures and measures; and, assuring confidence in the study's internal and external validity. An innovative sample design and/or sampling frame can be the centerpiece of a research design.

Examples of topics within research design include, but are not limited to, the following:

o Conceptual design strategies for the study of culture in the context of health. Culture may include but is not limited to ethnic group, professional affiliation (e.g., culture of biomedicine), or interaction of multiple sub-cultures within a health-related context.

o Designs to improve causal inference from non-experimental and quasi-experimental research.

o Research to improve the efficacy of multilevel designs (e.g., sample size estimation techniques).

o Methods for improving the design and evaluation of community-based, participatory research and intervention trials (e.g., health promotion/disease prevention programs).

o Conceptual, methodological, and ethical issues in designing studies that use different sources of information; for example, studies comparing self- and third-party reports (e.g., from participants' family or friends).

o Designs to improve and compare various approaches to economic analysis, including cost analysis, cost-effectiveness, cost-benefit, and conjoint analysis for improving decision-making in health policy and health care systems.

o Designs to improve the inclusion of underrepresented groups in research. Examples of these groups are women, children, the elderly, ethnic and racial minorities, sexual minority groups, and language minority populations - that is, individuals who do not speak the most common language or languages in a country or region (e.g., in the United States, individuals who speak neither English nor Spanish).

o Designs that will allow for the meaningful integration of biological, behavioral and social science data (e.g., the use of factorial designs to assess interacting and modulatory behavioral and neural systems).

o Methods for archiving and disseminating complex datasets, especially longitudinal datasets, datasets containing social network data, geographic identifiers, and/or biological measures so that the identities of study participants are protected and so that the datasets can be used by investigators who were not part of the original research team.

B. MEASUREMENT

Developing and validating research instruments and questions are vitally important for collecting reliable information, and have obvious impact on data validity and reliability. For example, health care practitioners must collect reliable reports of symptoms from their patients in order to accurately diagnose disease. In addition, data collection instruments and questions developed for a particular age, gender, or cultural group may not be valid for other groups. For example, a dietary history questionnaire developed for Americans of European descent may not contain the foods commonly eaten by Americans of African, Asian, or Hispanic descent. Methods to collect information regarding child rearing should take into account the fact that such practices will vary in different cultures. Finally, continued improvement and innovation in developing and validating data collection instruments are important for all types of research settings, ranging from the clinical interview and observational study to the survey.

Examples of measurement issues include, but are not limited to, the following:

o Development and refinement of measures/instruments/surveys used in behavioral and social science research that fill a gap in research needs, with a goal of developing and validating core sets of items to reduce redundancy across measures.

o Instrument design, calibration, and refinement; instrument design issues in studying age, gender, and culture, including methods of studying culture and self-identification of race/ethnicity, as well as the psychometric properties underlying data collection instruments.

o Measurement issues in using technology such as computer assisted data collection and web-based technology.

o Direct and indirect measurement of attitudes, values, self-esteem, and other psychological variables. This includes examination of economic values, including willingness-to-pay, as means of evaluating benefits, including health services.

o Development of instruments that assess not only degree of change, but also rate and variable direction of change.

o Development of instruments that measure behavior objectively or reduce self-report burden (e.g., development of the pedometer or accelerometer for the measurement of physical activity).

o Development of objective measures of components of the built environment that impact health and how people interact with those environmental components (e.g., measures of neighborhood design that may affect physical activity).

o Methodology to objectively measure the social environment (e.g., imaging devices to measure social interactions), including aspects of the community environment that impact health.

o Assessment of the relationship of self-report measures to behavioral, neural and other biological measures (because self-report routinely is used by health practitioners as a method of assessing physical and mental health).

C. DATA COLLECTION TECHNIQUES

Data collection techniques are the tools and procedures scientists use for implementing research designs and obtaining measurements. Methods for collecting research data have an important impact on data validity and reliability. For example, studies have suggested that use of self-administered instruments can facilitate the reporting of sensitive or illegal behaviors. Innovative methodologies can also lead to the collection of new or more complex types of data by behavioral scientists. For example, recent developments in computer-assisted interviewing have permitted more complex question sequences in survey research, and the development of hand-held "beepers" programmed for data entry have permitted the collection of time-specific data on activities such as cigarette smoking. In addition, implicit measures have allowed researchers to examine processes of which people themselves have been unaware. Continued improvement and innovation in data collection methods is important for all types of research settings,

including clinical interviews, observational studies, participatory action research, and surveys.

Potential topics within data collection techniques include, but are not limited to the following:

o Methods to improve data collection in surveys, epidemiologic self-report studies, ethnographic and other qualitative studies, participatory action research methods, and multimethod studies; this may include new approaches to instrument design and manipulation of method and mode of data collection, length, setting, and interpersonal factors in data collection exchanges.

o Methods to develop innovative gold standards to assess the accuracy of and improve the accuracy of self reports, in the absence of health record checks (a possible consequence of the Privacy Rule regulation of the Health Insurance Portability and Accountability Act of 1996).

o Development of web-based methods for collecting outcome data in randomized controlled trials and in observational studies.

o New methods for qualitative research; techniques for validating and replicating findings from qualitative research, including collection strategies, development of coding protocols, and techniques that facilitate the integration and validation of qualitative and quantitative measurement; optimal timing and integration of multiple quantitative and/or qualitative methodologies.

o Methods to reduce sampling, survey, and item non-response bias in research studies, including techniques to improve the coverage of relevant populations in household surveys, to increase the voluntary participation of eligible subjects, to reduce attrition in longitudinal studies and clinical trials, to improve response rates on sensitive items, and to impute missing values.

o Techniques for collecting contextual data (e.g., neighborhood composition, peer group characteristics, geographic and environmental information) and for operationalizing the boundaries of particular social, economic, physical, and cultural contexts.

o Development or refinement of varying technologies for data collection, including automated collection and reporting technologies, and research on how the method/mode used to collect data affects quality in a variety of populations, contexts and substantive areas.

o Data collection techniques that address the needs of special populations (e.g., physically or mentally disabled, non-literate populations, non-English speaking populations, the homeless and incarcerated, children and the elderly,

critically ill patients) and that address how these methods affect data quality and completeness across diverse populations.

o Development of research designs, sampling techniques, and statistical methods for studies that involve populations that are small or difficult to access.

D. ANALYTIC METHODS

Analytic methods encompass the concepts and techniques used in analyzing data and interpreting and reporting results. The goal of new and improved analytic methods is to help make estimation, hypothesis testing, and causal modeling based on scientific data as sound as possible. Challenges include developing techniques that distinguish underlying regularities from the noise created by variability and imprecise measurement; developing causal inferences from quasi-experimental or non-experimental data; improving both the internal validity and external validity (generalizability) of measures and studies; and developing appropriate analytic techniques for use with new kinds of data and new approaches to behavioral and social science research.

Examples of topics within analytic methods include, but are not limited to the following:

o Improved analysis of longitudinal data, in particular, the analysis of correlated data, the modeling of different sources of error, and techniques for dealing with missing data (as seen in the use of growth curve models for analyzing longitudinal data for each individual participant).

o Methods for improving the analysis of multicultural community-based multi-level intervention trials (e.g., health promotion/disease prevention programs).

o Improved methodology for the analysis of complex survey data, including the statistical modeling of non-response and other survey errors.

o Innovative techniques for improving causal inference from non-experimental research and for determination of if/when noise is really context.

o Analytic methods for integrating evidence from qualitative and quantitative research, such as research examining the complex relationships among multiple sources of information on a single construct (e.g., self- and third-party reports, clinical examinations and testing, laboratory tests, and other record sources).

o Analytic methods that appropriately model social structures, social processes, and spatial relationships such as social networks, social influence, diffusion, and contextual effects.

o Statistical procedures for accurately estimating multilevel models.

o Development of novel mathematical and computational techniques for analyzing and modeling behavioral and social processes.

o Methods for improving the analysis of non-independent data, such as data examining processes in interactions between couples, families, or other groups.

RELEVANT RESEARCH LINKS

Potential applicants specifically concerned with research regarding the inclusion of language minorities (e.g., people who do not speak the most common national language or languages) should also see the recent report on the conference "Diverse Voices - The Inclusion of Language-Minority Populations in National Studies: Challenges and Opportunities," sponsored by National Institute on Aging, the National Institute of Child Health and Human Development, and the National Center on Minority Health and Health Disparities: http://www.nichd.nih.gov/publications/pubs/diverse_voices.htm.

In June, 2000 the Office of Behavioral and Social Sciences Research (OBSSR) held a conference "Toward Higher Levels of Analysis: Progress and Promise in Research on Social and Cultural Dimensions of Health." In an agenda-setting activity that followed the conference, a panel of scientists developed an ambitious research agenda on the social and cultural dimensions of health. A program announcement based on the panel's recommendations for substantive research has been issued by the OBSSR and can be found at: http://grants.nih.gov/grants/guide/pa-files/PA-02-043.html. However, the research agenda also included detailed recommendations relating to needed methodological development to address the social and cultural dimensions of health. Potential applicants are encouraged to consult this report, available at http://obssr.od.nih.gov/Conf_Wkshp/higherlevel/conference.html

In September 2001, NIH sponsored an International Conference entitled: Stigma and Global Health: Developing a Research Agenda. One of the recommendations was to encourage research intended to develop methodological, evaluative and analytic tools for 1) studying stigma and its consequences with respect to health, and 2) development, evaluation and optimization of interventions to prevent or mitigate the negative effects of stigma and discrimination on health. In both areas it was recommended that the social and cultural dimensions of stigma and its manifestations be included. Applicants are encouraged to refer to the stigma conference website:
http://www.stigmaconference.nih.gov
for further resources and information.

Finally, the following reports may be useful as general references on behavior and social sciences research as it relates to health:

New Horizons in Health: An Integrative Approach. (2001). Burton H. Singer and Carol D. Ryff, Editors, Committee on Future Directions for Behavioral and Social Sciences Research at the National Institutes of Health, Board on Behavioral, Cognitive, and Sensory Sciences, National Research Council (http://www.nap.edu/catalog/10002.html).

Health and Behavior: The Interplay of Biological, Behavioral, and Societal Influences (2001). Committee on Health and Behavior: Research, Practice and Policy, Board on Neuroscience and Behavioral Health, Institute of Medicine (http://www.nap.edu/catalog/9838.html).

From Neurons to Neighborhoods: The Science of Early Childhood Development (2000). Jack P. Shonkoff and Deborah A. Phillips, Editors; Committee on Integrating the Science of Early Childhood Development, Board on Children, Youth, and Families, National Research Council (http://books.nap.edu/catalog/9824.html).

Bridging Disciplines in the Brain, Behavioral, and Clinical Sciences (2000). Terry C. Pellmar and Leon Eisenberg, Editors; Committee on Building Bridges in the Brain, Behavioral, and Clinical Sciences; Division of Neuroscience and Behavioral Health, Institute of Medicine (http://books.nap.edu/catalog/9942.html).

Expanding the Boundaries of Health and Social Science: Case Studies in Interdisciplinary Innovation (2003). Frank Kessel, Patricia Rosenfield and Norman Anderson, Editors. New York: Oxford University Press.

Rebuilding the Unity of Health and the Environment (2001). Kathi Hanna and Christine Coussens, Editors; Roundtable on Environmental Health Sciences, Research, and Medicine, Division of Health Sciences Policy, Institute of Medicine (http://www.nap.edu/books/030907259X/html/).

Cells and Surveys. Should Biological Measures be Included in Social Science Research? (2001). Caleb E. Finch, James W. Vaupel and Kevin Kinsella, Editors; Committee on Population, National Research Council (http://www.nap.edu/books/0309071992/html/).

Applicants may also wish to consult the following report on the protection of human subjects in behavioral and social sciences research:

Protecting Participants and Facilitating Social and Behavioral Sciences Research (2003). Constance F. Citro, Daniel R. Ilgen, and Cora B. Marrett, Editors, Panel on Institutional Review Boards, Surveys, and Social Science Research, National Research Council (http://www.nap.edu/books/0309088526/html/).

MECHANISM OF SUPPORT

This RFA will use the NIH competing supplement mechanism to ongoing R01, P01, R21 or U01 grants. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. This RFA uses just-in-time concepts. It also uses the modular budgeting format (see http://grants.nih.gov/grants/funding/modular/modular.htm). Since the direct costs of the supplements will always be less than $250,000 yearly, the modular format is required. This program does not require cost sharing as defined in the current NIH Grants Policy Statement at http://grants.nih.gov/grants/policy/nihgps_2001/part_i_1.htm.

FUNDS AVAILABLE

The NIH intends to commit approximately $600,000 in FY 2004 to fund 4-6 competitive supplements in response to this RFA. Support will be offered for a maximum of two years through competing supplements to existing grants. Requests should not exceed $150,000 total direct costs for the entire two years of support. Facilities and Administrative (F&A) costs are limited to 8 percent of allowable direct costs.

As the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of supplements will vary, but in any case are non-renewable; continuation of projects developed under this program must be through other grant mechanisms. Awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. The number of awards made will depend on institutional need, the number of highly meritorious applications received, and the size of individual awards.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories
- o Units of State and local governments
- o Eligible agencies of the Federal government
- o Domestic or foreign institutions/organizations

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Because this grant will be awarded as a supplement to existing NIH-funded research project grants (R01), program projects (P01), exploratory/developmental grants (R21), or cooperative agreements (U01), only current Principal Investigators of an active award are eligible to be the Principal Investigators of a proposal submitted in response to this RFA. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

SPECIAL REQUIREMENTS

Grants that are eligible for supplementation in response to this RFA are NIH-funded R01, P01, R21 and U01 grants whose project end dates are September 30, 2005 or later. The existing grant must have at least 12 months of support remaining on September 30, 2004, the anticipated start date of the supplement award. A supplemental application will not be accepted until after the original application for the parent grant has been awarded, and the supplement may not extend beyond the term of the parent grant. The PI must be the same individual as on parent grant. The work should be a logical extension of the goals and objectives of the parent grant, but should constitute new methodological development. A research plan redundant with any portion of the studies approved under the parent grant will not be supported under this supplement program. Applicants are strongly encouraged to consult with program staff from the appropriate awarding component of the parent grant prior to submitting an application for a supplement.

Annual project reports and final reports of the parent project should include a specific discussion of the progress made from the supplemental award.

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this RFA and welcome the opportunity answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

o Direct your general questions about scientific/research issues to:

Deborah H. Olster, Ph.D.
Office of Behavioral and Social Sciences Research
National Institutes of Health
One Center Drive, Room 256
Bethesda, MD 20892-0183
Telephone: (301) 451-4286
Fax: (301) 402-1150
Email: olsterd@od.nih.gov

Rebecca L. Clark, Ph.D.
Demographic and Behavioral Sciences Branch (DBSB)
Center for Population Research (CPR)
National Institute of Child Health and Human Development (NICHD)
6100 Executive Boulevard, Room 8B07, MSC 7510
Bethesda, MD 20892-7510
Telephone: 301-496-1175
Fax: 301-496-0962
E-mail: rclark@mail.nih.gov

o Direct your questions about peer review issues to:

Anita Miller Sostek, Ph.D.
Division Director
Clinical and Population-Based Studies
Center for Scientific Review
6701 Rockledge Drive, Room 4100, MSC 7814
Bethesda, MD 20892 (20817 for overnight mail)
Telephone: (301) 435-1260
FAX: (301) 480-2644
Email: sosteka@mail.nih.gov

o Direct your questions about financial or grants management matters to:

Annette Hanopole
Grants Management Branch
National Institute of Child Health and Human Development
6100 Executive Boulevard, 8A01, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 435-6975
FAX: (301) 402-0915
E-mail: ah23k@nih.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

o Descriptive title of the proposed research (same as parent grant)
o Name, address, and telephone number of the Principal Investigator
o Names of other key personnel
o Participating institutions
o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential workload and plan the review.

The letter of intent is to be sent by January 13, 2004. The letter of intent should be sent to:

Rebecca L. Clark, Ph.D.
Demographic and Behavioral Sciences Branch (DBSB)
Center for Population Research (CPR)
National Institute of Child Health and Human Development (NICHD)
6100 Executive Boulevard, Room 8B07, MSC 7510

Bethesda, MD 20892-7510
Telephone: 301-496-1175
Fax: 301-496-0962
E-mail: rclark@mail.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001), according to the SUPPLEMENTARY INSTRUCTIONS described below. Applications must have a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number can be obtained by calling (866) 705-5711 or through the web site at http://www.dunandbradstreet.com/. The DUNS number should be entered on line 11 of the face page of the PHS 398 form. The PHS 398 document is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

SUPPLEMENTARY INSTRUCTIONS

To apply for a competitive supplement, the PI must submit the following information:

o A completed Grant Application PHS 398 with appropriate signatures on the face page. Include the title and grant number of the parent grant on line 1 and the RFA Number of this program on line 2.

o Applications should have the normal Description on page 2 as described in PHS 398 which should describe the proposed supplemental activity and how it relates to the parent grant.

o A one page introduction, prepared by the Principal investigator, that includes the grant number of the funded grant or project, summary or abstract, and specific aims.

o The Research Plan should provide a description of the supplemental project, including:

a. A description of the methodological development being proposed, how it is innovative or critical to advancing the state of the science in the field.

b. A description of how the proposed methodological development advances the specific research goals and objectives of the parent grant.

c. A description of the overall impact the proposed methodology will have on the general scientific field, and on future research efforts to integrate behavioral and social sciences in the study of health.

IT IS A REQUIREMENT THAT SECTIONS A-D OF THE RESEARCH PLAN NOT EXCEED 10 PAGES.

o In addition to completing all portions of the PHS 398, applicants should also include a cover letter requesting the competing supplement and identifying this RFA.

o Facilities and Administrative (F&A) Costs: These costs are limited to 8 percent of allowable direct costs.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS: All applications must be submitted in a modular grant format. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in $25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at http://grants.nih.gov/grants/funding/phs398/phs398.html includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at http://grants.nih.gov/grants/funding/modular/modular.htm.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/labels.pdf.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the checklist, five signed photocopies, and appendix materials in one package to:

Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be received on or before the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the

applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to an RFA, it is to be prepared as a NEW application. That is, the application for the RFA must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes from the previous unfunded version of the application.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NICHD. Incomplete and/or nonresponsive applications will not be reviewed. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score
o Receive a written critique
o Receive a second level review by an appropriate National Advisory Council or Board.

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application.

o Significance
o Approach
o Innovation
o Investigator
o Environment

The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

SIGNIFICANCE: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

INNOVATION: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

INVESTIGATOR: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

ENVIRONMENT: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

ADDITIONAL REVIEW CRITERIA

In addition to the above criteria, the following items will be considered in the determination of the scientific merit and the priority score:

o The benefits of the methodological development to the aims of the parent grant;
o The potential application of the methodological innovation to other health research;
o The broad impact of the methodological innovation to the general scientific field;
o The quality of the innovation and the potential benefits the innovation may provide (e.g., the need for objective versus subjective measures; the potential increase in research capacity or data collection efficiency; the potential to improve reliability or validity, etc.).

Each application is not expected to focus on all four of the areas identified for methodological development (i.e., research design, measurement, data collection techniques, analytic methods). An application that focuses on only one of these areas may still be competitive.

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISK: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed. (See criteria included in the section on Federal Citations, below).

INCLUSION OF WOMEN, MINORITIES AND CHILDREN IN RESEARCH: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria in the sections on Federal Citations, below).

CARE AND USE OF VERTEBRATE ANIMALS IN RESEARCH: If vertebrate animals are to be used in the project, the five items described under Section f of the PHS 398 research grant application instructions (rev. 5/2001) will be assessed.

ADDITIONAL REVIEW CONSIDERATIONS

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: January 13, 2004
Application Receipt Date: February 13, 2004
Peer Review Date: June/July, 2004
Council Review: September, 2004
Earliest Anticipated Start Date: September 30, 2004

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

o Scientific merit (as determined by peer review)
o Availability of funds
o Programmatic priorities.

REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

DATA AND SAFETY MONITORING PLAN: Data and safety monitoring is required for all types of clinical trials, including physiologic, toxicity, and dose-finding studies (phase I); efficacy studies (phase II); efficacy, effectiveness and comparative trials (phase III). The establishment of data and safety monitoring boards (DSMBs) is required for multi-site clinical trials involving interventions that entail potential risk to the participants. (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate

with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html); a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at http://grants.nih.gov/grants/funding/children/children.htm

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem

Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide, in the project description and elsewhere in the application as appropriate, the official NIH identifier(s) for the hESC line(s)to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION: The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.healthypeople.gov/.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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